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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,876	04/11/2005	Dieter Dorsch	MERCK-2998	2264

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EXAMINER

CHENG, KAREN

ART UNIT	PAPER NUMBER
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1626

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/530,876

Applicant(s)

DORSCH ET AL.

Examiner

Karen Cheng

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 1-20 (in part), 21, 22(in part), 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1-2 (in part), 3, 4-20 (in part), 22 (in part) is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-23 are currently pending in the instant application. Claims 1-20 (in part), 21, 22 (in part) and 23 have been withdrawn from consideration as being drawn to non-elected subject matter.

Re-statement of Response to Election/Restrictions

Applicant's election with traverse of the subject matter of claims 1-15 and 17-20, drawn to compounds of formula I and/or pharmaceutically usable derivatives, solvates, and stereoisomers thereof, wherein X is NR^3 , R^1 is A which is an unbranched or branched alkyl having 1-10 C atoms, Y is Ar-diyl, D is a thienyl ring which is mono- or disubstituted by Hal, T is morpholin-4-yl which is monosubstituted by carbonyl oxygen(=O), and W is as defined in the reply filed on 11/01/2006 was acknowledged. As stated in the Non-Final Rejection, mailed 12/22/06, the restriction requirement was still deemed proper as the Examiner had established that unity of invention was lacking. As a result, the elected and examined subject matter was stated to be compounds of formula I wherein X is NR^3 , R^1 is as defined, Y is cycloalkylene, Het-diyl or Ar-diyl, D is a thienyl ring which is mono- or disubstituted by Hal, A, OR^2 , $\text{N}(\text{R}^2)_2$, NO_2 , CN, COOR_2 or $\text{CON}(\text{R}^2)_2$, T, W, and the other variables are as defined. Claims 16-20 and 22 drawn to processes and methods of use of compounds of the scope described above were rejoined and examined.

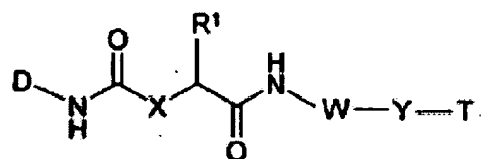
Status of the Claims

Claims 1-23 are pending in this application. **Claims 21 and 23** are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions

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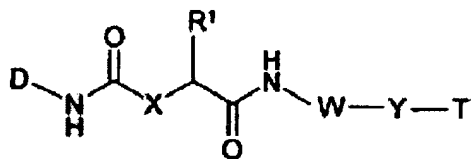
under 37 CFR § 1.142(b). The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search and examination considerations. In addition, a reference that anticipates one invention would not render obvious the other invention.

The scope of the invention of the elected and examined subject matter are compounds of **Claims 1-20 and 22** which are drawn to the core structure of



wherein D is a thienyl ring substituted as defined, X is NR³, Y is cycloalkylene, Het-diyl or Ar-diyl, R¹, R², R³, W, T and the other variables are as defined, pharmaceutically acceptable salts, solvates, and stereoisomers thereof, pharmaceutical compositions, a process for preparation of said compounds, a method of inhibiting coagulation factor Xa and VIIa, and a kit comprising compounds of the core structure describe above.

As a result of the election and the corresponding scope of the invention, identified supra, the remaining subject matter of **Claims 1-20 and 22** that all have the core structure of



wherein D is an aromatic five-membered heterocyclic ring other than a thienyl ring, X is O, Y is alkylene, and the other variables are as defined are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to non-elected inventions.

The scope of the invention of the non-elected and non-examined subject matter includes the compounds described in the paragraph immediately above as well as pharmaceutically acceptable salts, solvates, and stereoisomers thereof, pharmaceutical compositions, a process for preparation of said compounds, methods of inhibiting coagulation factor Xa and VIIa, and a kit drawn to compound of said core structure.

The withdrawn compounds contain the variety of cores, which are patentably distinct from the elected and examined core, and are chemically recognized to differ in structure, function, and reactivity. Therefore, the subject matter, which has been withdrawn from consideration as being *non-elected* subject matter materially, differs in structure and composition from the elected/examined subject matter so that a reference that anticipates the elected/examined subject matter would not render obvious the *non-elected* subject matter.

This recognized chemical diversity of the functional groups is apparent by the different fields of search required for the *non-elected* species versus the elected compounds. All compounds falling outside the search strategy of the elected compound and the structure shown above are heretofore directed to *non-elected* subject matter and are withdrawn from consideration under 35 U.S.C. § 121 and 37 C.F.R. § 1.142(b). It is suggested that in order to advance prosecution, the non-elected subject matter be canceled when responding to this Office Action.

Response to Amendment and Arguments

Applicant's amendments filed on 03/22/07 has overcome the following objections and rejections:

- The 35 USC 112 1st paragraph rejections of claims 1-14, 16, 19-20 and 22 have been overcome by the amendment to the claims that delete "pharmaceutically usable derivatives" and insert acceptable salt in place.
- The 35 USC 112 2nd paragraph rejections of claims 20 and 22 have been overcome by the amendment to the claims that delete "at least one further medicament active ingredient" and insert an excipient, adjuvant, or vitamin in place.
- The objections to claims 17 and 18 as being substantial duplicates have been overcome by amendment.
- The objection to the specification has been overcome by amendment.

Maintained Claim Objections

Claims 1-20 (in part) and 22 (in part) are objected to because of the following informalities: they contain or are dependent on subject matter that has been withdrawn from consideration. Appropriate correction is required. Specifically Claims 1-2, 6, 13-16 contain subject matter that has been withdrawn.

New Claim Objections

Claim 3 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 2. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is

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proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Since the subject matter of this invention is drawn to D is thienyl, claims 2 and 3 would encompass the same subject matter.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

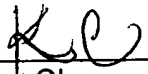
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cheng whose telephone number is 571-272-6233. The examiner can normally be reached on M-F, 9AM to 5:30PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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